

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
26 July 2001 (26.07.2001)

PCT

(10) International Publication Number  
WO 01/52727 A1

(51) International Patent Classification<sup>7</sup>: A61B 5/00      (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(21) International Application Number: PCT/US01/01670

(22) International Filing Date: 17 January 2001 (17.01.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
09/487,423      20 January 2000 (20.01.2000) US

(71) Applicant: MINIMED INC. [US/US]; 18000 Devonshire Street, Northridge, CA 91325 (US).

(72) Inventors: CAUSEY, James, D., III; 2107 Cushman Court, Simi Valley, CA 93063 (US). PURVIS, Richard, E.; 991 Palm Terrace, Pasadena, CA 91104 (US). HENKE, James; 5105 E. Los Angeles Avenue, PMB 168, Simi Valley, CA 93063 (US).

(74) Agent: KOVELMAN, Paul, H.; MiniMed Inc., 18000 Devonshire Street, Northridge, CA 91325-1219 (US).

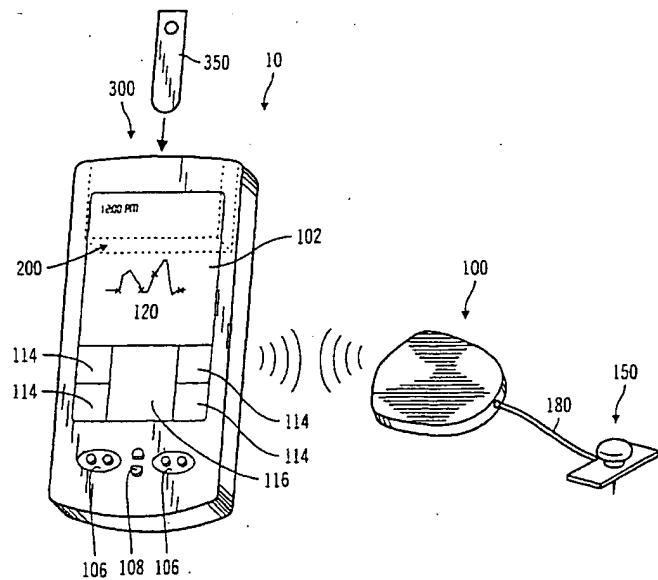
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: HANDHELD PERSONAL DATA ASSISTANT (PDA) WITH A MEDICAL DEVICE AND METHOD OF USING THE SAME



WO 01/52727 A1

(57) Abstract: A medical device module for use in a system with a personal data assistant (PDA) with at least one medical device includes a housing, at least one medical device and a processor. The housing is adapted to couple with the PDA. The at least one medical device interface is coupled to the housing for interfacing with the at least one medical device. The processor is coupled to the at least one medical device interface to process data from the at least one medical device. The processor is also capable of interfacing with the PDA.

TITLE

Handheld Personal Data Assistant (PDA) With A Medical Device And  
Method Of Using The Same

5    FIELD OF THE INVENTION

This invention relates to handheld personal data assistant (PDA) for use with medical devices and, in particular embodiments, to a PDA that includes a medical device to facilitate testing and monitoring of a patient's condition with coordination of data management and programming through the PDA.

10

BACKGROUND OF THE INVENTION

Over the years, bodily characteristics have been determined by obtaining a sample of bodily fluid. For example, diabetics often test for blood glucose levels with a blood glucose meter. Traditional blood glucose determinations have 15 utilized a painful finger stick using a lancet to withdraw a small blood sample that is used by the blood glucose meter. This results in discomfort from the lancet as it contacts nerves in the subcutaneous tissue. To obtain a measure of control or information on a diabetic's condition, several finger sticks and tests are required each day (8 or more such tests a day are not uncommon). The pain of lancing and 20 the cumulative discomfort from multiple needle sticks is a strong reason why patients fail to comply with a medical testing regimen used to determine a change in characteristic over a period of time. In addition, these blood glucose meters are only designed to provide data at discrete points, and even with multiple tests a day, do not provide continuous data to show the variations in the characteristic 25 between testing times.

A variety of implantable electrochemical sensors for use with monitors have been developed for detecting and/or quantifying specific agents or compositions in a patient's blood. For instance, glucose sensors have been developed for use in obtaining an indication of blood glucose levels in a diabetic 30 patient. Such readings are useful in monitoring and/or adjusting a treatment regimen which typically includes the regular administration of insulin to the patient. Thus, blood glucose readings from the monitor improve medical

therapies with semi-automated medication infusion pumps of the external type, as generally described in U.S. Patent Nos. 4,562,751; 4,678,408; and 4,685,903; or automated implantable medication infusion pumps, as generally described in U.S. Patent No. 4,573,994, which are herein incorporated by reference. Typical thin film sensors are described in commonly assigned U.S. Patent Nos. 5,390,671; 5,391,250; 5,482,473; and 5,586,553 which are incorporated by reference herein. See also U.S. Patent No. 5,299,571. However, the monitors and electrochemical sensors often require calibration using readings obtained from blood glucose meters to augment and adjust for drift over time. Thus, although the monitors and electrochemical sensors provide more accurate trend information, a separate blood glucose meter is still often required.

A user must often carry multiple devices to test different aspects of the same value or characteristic. For instance, the a user would need a blood glucose meter and blood glucose monitor. In addition, individuals are also carrying other electronic devices, such as an infusion device, cellular telephones, personal entertainment systems (such as radios, cassette players, CD players, or the like). They may also include small personal computers, personal data assistants (PDAs) or the like. Thus, users often carry a large number of separate electronic devices, which can be cumbersome and inconvenient to handle.

20

#### SUMMARY OF THE DISCLOSURE

It is an object of an embodiment of the present invention to provide an improved personal data assistant (PDA) that includes a characteristic monitor and/or a characteristic meter, which obviates for practical purposes, the above mentioned limitations.

According to an embodiment of the present invention, a medical device module for use in a system with a personal data assistant (PDA) with at least one medical device includes a housing, at least one medical device and a processor. The housing is adapted to couple with the PDA. The at least one medical device interface is coupled to the housing for interfacing with the at least one medical device. The processor is coupled to the at least one medical device interface to process data from the at least one medical device. The processor is also capable

of interfacing with the PDA.

In preferred embodiments, the at least one medical device is a characteristic sensor that produces a signal indicative of a characteristic of a user, and the medical device module further includes a second characteristic determining device within the housing for receiving and testing an analyte to determine the quantity of the analyte independently of the at least one characteristic sensor. The at least one medical device interface is a sensor receiver to receive sensor data signals produced from the at least one characteristic sensor. The processor is coupled to the sensor receiver and the second characteristic determining device to process the determined quantity of the analyte from the second characteristic determining device and the sensor data signals from the at least one characteristic sensor.

In particular embodiments, the at least one characteristic sensor is remotely located from the medical device module, and the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor. In other embodiments, the medical device module further includes a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device. In additional embodiments, the medical device module uses a display of the PDA to show the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor. In further embodiments, the processor monitors the sensor data signals from the sensor receiver to determine when the second characteristic determining device is to be used to perform calibration of the sensor data signals.

In other embodiments, the medical device module further includes a memory to store the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor. In still other embodiments, the sensor data signals are received by the sensor receiver continuously, near continuously or intermittently.

In yet another embodiments, the second characteristic determining device is a second medical device module that utilizes a second characteristic sensor. In

these embodiments, the determined quantity of the analyte from the second characteristic determining device is determined continuously, near continuously or intermittently. In a further embodiment, the second medical device module and the second characteristic sensor use a different sensing technology from that used by the at least one medical device module and the characteristic sensor.

5 In still yet another embodiment of the present invention, the second characteristic determining device utilizes a discrete sample to determine the quantity of the analyte. In further embodiments, the second characteristic determining device utilizes a test strip to analyze the sample to determine the 10 quantity of the analyte. In still further embodiments, the at least one medical device is an infusion device, an analyte sensor patch and/or more than one medical device.

15 Still other preferred embodiments of the present invention are directed to a personal data assistant (PDA) for interfacing with at least one medical devices described above. In these embodiments, the medical device module operatively couples with the PDA and the PDA includes a housing adapted to receive the medical device module.

20 Further preferred embodiments of the present invention are directed to a medical device module for use in a system with a personal data assistant (PDA) with at least one characteristic sensor that produces a signal indicative of a characteristic of a user. The medical device module includes a housing, a test strip receptacle, a sensor receiver and a processor. The housing is adapted to operatively couple with the PDA. The test strip receptacle for receiving and testing a test strip exposed to an analyte to determine the quantity of the analyte. 25 The sensor receiver is for receiving sensor data signals produced from the at least one characteristic sensor. The processor is coupled to the sensor receiver and the test strip receptacle to process the determined quantity of the analyte from the test strip receptacle and the sensor data signals from the at least one characteristic sensor, and the processor is capable of interfacing with the PDA.

30 In particular embodiments, the at least one characteristic sensor is remotely located from the medical device module, and wherein the sensor receiver receives the sensor data signals as wireless signals from the remotely

located at least one characteristic sensor. In other embodiments, the medical device module further includes a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device.

Preferably, the transmitter transmits the processed sensor signals by radio

5 frequencies. In additional embodiments, the transmitter transmits through a relay device between the transmitter and a remotely located processing device.

Preferably, the relay device increases a maximum distance by amplifying the processed sensor data signals from the transmitter to be received by the remotely located processing device. Alternatively, the relay device enables the remotely

10 located processing device to be located in a different room than the transmitter.

In other alternative embodiments, the relay device includes a telecommunications device, and when the transmitter generates an alarm the telecommunications device transmits the alarm to a remotely located receiving station.

In further embodiments, the processor of the medical device module

15 further includes the ability to program other medical devices, and wherein the transmitter transmits a program to the other medical devices. In still other embodiments, the medical device module further includes a data receiver, and the data receiver receives program instructions from other processing devices.

In yet another embodiment, the medical device module uses a display on  
20 the PDA to show the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor. In still other embodiments, the processor of the medical device module the sensor data signals from the sensor receiver to determine when the test receptacle is to be used to perform calibration of the sensor data signals.

25 Additional embodiments of the medical device module further include a memory to store the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor. In particular embodiments, the sensor data signals are received by the sensor receiver continuously, near continuously or intermittently.

30 Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, various features of embodiments of

the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of embodiments of the invention will be made with

5 reference to the accompanying drawings, wherein like numerals designate corresponding parts in the several figures.

Fig. 1 is a perspective view of a system using a handheld data assistant (PDA) and computer in accordance with an embodiment of the present invention.

Fig. 2 is a perspective view of a PDA with a medical device module in  
10 accordance with an embodiment of the present invention.

Fig. 3 is a bottom plan view of the PDA and medical device shown in Fig.  
2.

Fig. 4 is a perspective view of the PDA including a medical device module that includes a characteristic monitor and characteristic meter and that  
15 interfaces with a telemetered characteristic monitor transmitter in accordance with a first embodiment of the present invention.

Fig. 5 is a block diagram of the medical device module that includes the characteristic monitor and the characteristic meter shown in Fig. 4.

Fig. 6 is a perspective view of the medical device module that includes the  
20 characteristic meter and characteristic monitor that interfaces with a telemetered characteristic monitor transmitter in accordance with the embodiment of Figs. 4 and 5.

Fig. 7 is a perspective view of a PDA including a medical device module that includes a characteristic meter, characteristic monitor that interfaces with a  
25 telemetered characteristic monitor transmitter, and an infusion device in accordance with a second embodiment of the present invention.

Fig. 8 is a perspective view of the medical device module that includes the characteristic meter and characteristic monitor that interfaces with a telemetered characteristic monitor transmitter and interfaces with the infusion device in  
30 accordance with the embodiment of Fig. 7.

Fig. 9 is a simplified block diagram of a telemetered characteristic monitor transmitter and medical device module in accordance with a third

embodiment of the present invention.

Fig. 10 is a simplified block diagram of a telemetered characteristic monitor transmitter and medical device module system in accordance with a fourth embodiment of the present invention.

5 Fig. 11 is a perspective view of a medical device module that interfaces with a telemetered characteristic monitor transmitter in accordance with a fifth embodiment of the present invention.

Fig. 12 is a perspective view of a medical device module that interfaces with a characteristic meter in accordance with a sixth embodiment of the present  
10 invention.

Fig. 13 is a perspective view of a medical device module that interfaces with an infusion device, telemetered characteristic monitor transmitter and a characteristic meter in accordance with a seventh embodiment of the present invention.

15 Fig. 14 is a perspective view of a medical device module that includes a characteristic meter and interfaces with an infusion device in accordance with an eighth embodiment of the present invention.

Fig. 15 is a perspective view of a medical device module that includes a characteristic meter in accordance with a ninth embodiment of the present  
20 invention.

Fig. 16 is a perspective view of a medical device module that interfaces with an infusion device in accordance with a tenth embodiment of the present invention.

25 Fig. 17 is a perspective view of a medical device module that interfaces with an implantable medical device in accordance with a tenth embodiment of the present invention.

Fig. 18 is a perspective view of a medical device module that includes a input jack for a wired connection with a medical device in accordance with an eleventh embodiment of the present invention.

30 Fig. 19 is a perspective view of a medical device module that interfaces with an implantable analyte sensing patch in accordance with a twelfth embodiment of the present invention.

Fig. 20 is a perspective view of a medical device module that includes contacts for interfacing with a medical device in accordance with a thirteenth embodiment of the present invention.

5    DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the invention is embodied in a handheld personal data assistant (PDA) that includes a medical device module for interfacing with a medical device. In preferred embodiments, medical device module interfaces with a characteristic monitor that obtains data  
10 from a telemetered characteristic monitor transmitter connected to a sensor set that determines body characteristics on a continuous, near continuous or intermittent basis. In further embodiments of the present invention, the medical device module interfaces with a characteristic meter for obtaining discrete measurements. In particular embodiments, the measurements received from the  
15 characteristic meter can be utilized by a characteristic monitor for calibration and/or data analysis and verification. In preferred embodiments, the characteristic monitor interfaces with a telemetered characteristic monitor transmitter that uses a sensor set and is for determining glucose levels in the blood and/or bodily fluids of the user. Preferably, the characteristic meter is primarily adapted for use with  
20 test strips that use a blood sample to determine glucose levels. However, other embodiments of the characteristic meter may use other testing structures, such as liquid samples placed in a receptacle, or the like, or test strips that use samples from other fluids, such as interstitial fluid, spinal fluid, saliva, urine, tears, sweat, or the like. However, it will be recognized that further embodiments of the  
25 invention may be used to interface with other telemetered characteristic monitors transmitters and/or meters to determine the levels of other agents, characteristics or compositions, such as hormones, cholesterol, medication concentrations, viral loads (e.g., HIV), or the like. In preferred embodiments, the characteristic monitor and sensor are primarily adapted for use with subcutaneous human tissue.  
30 However, still further embodiments may be placed in other types of tissue, such as muscle, lymph, organ tissue, veins, arteries or the like, and used in animal tissue. Other embodiments of the present invention may interface with other

medical devices, such as pacemakers, implanted analyte sensor patches, infusion devices, telemetry devices, or the like.

Fig. 1 is a perspective view of a system 1 using a handheld data assistant (PDA) 10 and computer 12 in accordance with an embodiment of the present

5 invention. Preferred embodiments, use a PDA 10 such as the Visor 1003E by Handspring. However, alternative embodiments, may use standard or customized personal data assistants such as, but not limited to, the Palm Pilot, Palm III, Palm V and/or Palm VII by Palm Computing a division of 3 COM, the PCS NP 1000 by Sprint, the pdQ 1900 by Qualcomm, the AutoPC by Clarion, Newton by  
10 Apple, the Cassiopeia by Casio, Blackberry by Research In Motion Limited, or the like. In preferred embodiments, the computer 12 includes a computer processing unit 14, a monitor 16, a key board 18 and a mouse 20. The computer 12 also includes a PDA cradle 22 connected to the computer 12 by a cable 24 to provide two-way data communication between the PDA 10 and the computer 12.  
15 In alternative embodiments, the PDA cradle 22 may connect to the computer using a wireless connection. In further alternative embodiments, the PDA cradle 22 may be omitted and the PDA 10 includes a receiver and transmitter and/or a jack to provide the two-way communication between the PDA 10 and the computer 12. In further alternative embodiments, the computer 12 may be  
20 replaced with a different processing device, such as a data processor, a laptop computer, a modem or other connection to a network computer server, an internet connection, or the like.

Figs. 2 and 3 are views of a PDA 10 with a medical device module 200 in accordance with an embodiment of the present invention. The PDA 10 includes a  
25 display 102 mounted in a case 104. The case includes a plurality of physical keys 106 and 108 to activate and control various features on the PDA 10. The display 102 of the PDA 10 is a touch screen LCD that allows the display of various icons 110 representative of different programs available on the PDA 10. The icons 110 on the display 102 may be activated by finger pressure or the touch of a stylus  
30 112. The display 102 may also be used to show graphs, tabular data, animation, or the like. The display 102 also includes a region with hard icons 114 that represent regular program activating features and a writing area 116 for entering

data using the stylus 112. Preferred embodiments of the PDA 10 are adapted for use of the Palm computing software and standards developed by 3 Com. However, alternative embodiments may use computing software and standards produced by other companies.

5 As shown in Fig. 3, the PDA 10 has a slot 120 formed in the back 124 of the case 104 of the PDA 10 for receiving the medical device module 200. The slot 120 includes connector contacts 122 that mate with corresponding contacts 222 on the medical device module 200. Thus, the PDA 10 provides a standard user interfaces, including standard PDA features and programmability, that the  
10 user knows and understands. A medical device manufacturer primarily only needs to design, build and qualify a medical device module that interfaces with a standard PDA 10 interface and uses the existing hardware of the PDA 10 to interact with the user. Therefore, a medical device manufacturer focuses primarily on a medical device module that can be interchanged by the user to  
15 provide the user with a desired capability or function on a known and/or familiar device, the PDA 10. Further embodiments (not shown) may use multiple medical device modules or a medical device module that includes more than one medical device sub-module.

Fig 4 illustrates a perspective view of a PDA 10, in accordance with a  
20 preferred embodiment of the present invention. The PDA 10 includes a subcutaneous sensor set 150 (i.e., a sensor portion is implanted in, for example, dermal subdermal, subcutaneous tissues, or the like), a telemetered characteristic monitor transmitter 100 connected to the sensor set 150 through a sensor cable/connector 180, and a medical device module 200 that includes a  
25 characteristic monitor 200' and a characteristic meter 300. The subcutaneous sensor set 150 utilizes an electrode-type sensor, as described in more detail in U.S. Patent No. 5,391,250, entitled "Method Of Fabricating Thin Film Sensors", U.S. Pat. No. 5,482,473, entitled "Flex Circuit Connector", U.S. Patent No. 5,390,671, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent No.  
30 5,568,806, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent No. 5,586,553, entitled "Transcutaneous Sensor Insertion Set", U.S. Patent No. 5,779,655, entitled "Transducer Introducer Assembly" and co-pending U.S.

Patent No. 5,954,643, entitled "Insertion Set for a Transcutaneous Sensor," all of which are herein incorporated by reference. However, in alternative embodiments, the sensor may use other types of sensors, such as chemical based, optical based, or the like. In further alternative embodiments, the sensors may be 5 of a type that is used on the external surface of the skin or placed just below the skin layer of the user. Preferred embodiments of a surface mounted sensor would utilize interstitial fluid harvested from underneath the skin.

The telemetered characteristic monitor transmitter 100 generally includes the capability to transmit data. However, in alternative embodiments, the 10 telemetered characteristic monitor transmitter 100 may include a receiver, or the like, to facilitate two-way communication of data reading between the sensor set 150 and the characteristic monitor 200' of the medical device module 200. The characteristic monitor 200' in the medical device module 200 utilizes the transmitted data to determine the characteristic reading. Although a telemetered 15 approach that utilizes RF is preferred, other wireless techniques, such as optical, IR, ultrasonic, or the like may be used. In addition, wired connections may be utilized instead of a telemetered transmission of data from the sensor 150 to the medical device module 200 (see Fig. 18 below).

The characteristic meter 300 utilizes test strips 350, or the like, with a 20 sample obtained from the body of the patient to determine a characteristic (or analyte level) in a user at a discrete point in time. The discrete measurement from the characteristic meter 300 is stored in a memory of the medical device module 200 and may be used to calibrate the characteristic monitor 200' in the medical device module 200 against the test results from the characteristic meter 300, 25 either in real time or using a post calibration in either the characteristic monitor 200' in the medical device module 200 or during later analysis and review once the test results have been downloaded to a separate computer, communication station, or the like. Possible characteristic meters 300 that may be used are produced by Roche Diagnostics, Bayer Corporation, Abbott Medisense, Johnson 30 & Johnson, Mercury Diagnostics, Chronimed, or the like.

Fig. 5 illustrates a simplified flow block diagram of the medical device module 200 shown in Figs. 4 and 6. As shown in Fig. 5, the medical device

module 200 includes the characteristic meter 300 and also the characteristic monitor 200' that interfaces with a sensor set 150. The medical device module 200 includes a keypad interface 202, a ROM 204, a RAM 206, a display interface 208, a data Input and Output (I/O) port 210 that uses the contacts 222 on the 5 medical device module 200 to connect with the contacts 122 on the PDA 10, a sensor monitor 212, a sensor interface 214, a microprocessor 216, and a battery and/or power supply 218. An overlapping subset of these elements is used to process the data from the sensor 150 and is collectively shown as the characteristic monitor 200'. The characteristic meter 300, included in the medical 10 device module 200, includes a characteristic test meter 302 and a test interface 304.

The microprocessor 216 of the medical device module 200 is activated in several different ways. The keypad interface 202 is coupled directly to the microprocessor 216 and is useable to activate the microprocessor 216 upon 15 activation of the keys 106 and 108 and/or display 102 of the PDA 10. The microprocessor 216 is then prepared to store relevant information concerning the sensor data, meter readings, event data, or the like. For instance, the microprocessor 216 will store, the time, the date and the analyte level from a test strip 350 or may be used to record an independent event by the user. In addition, 20 the keypad interface 202, unpin interfacing with the PDA 10, may be used to activate and control the microprocessor 216 to perform analysis, calibration, control the display interface 208 and display 102, download stored data and results, upload program instructions, or the like. The microprocessor 216 may also be activated by receiving a specified signal from the sensor interface 214 25 indicating connection or receipt of data from a sensor 150 and/or by insertion of a test strip 350 into the test interface 304 of the included characteristic meter 300. Once activated, the microprocessor 216 stores data, analyzes signal values, tests results for accuracy, calibrates, downloads data, presents data for review and analysis, provides instructions, warnings and alarms, or the like.

30 The microprocessor 216 is coupled to a ROM 204 and a RAM 206. In preferred embodiments, the ROM 204 is an EPROM and the RAM 206 is a static RAM; however, other comparable memory storage components such as dynamic

RAM, non-static RAM, rewritable ROMs, flash memory, or the like, may be used. Generally, the ROM 204 stores the programs used by the microprocessor 216 to determine various parameters, such as the amount of an analyte corresponding to a received signal value in the sensor monitor 212 signal value,

5 calibration techniques for adjusting the sensor signals from the sensor 150, characteristic meter 300 operation and correspondence of test results with the sensor signal values, the date and the time, and how to report information to the user. The RAM 206 is used by the microprocessor 216 to store information about the sensor signal values and test strip 350 test results for later recall by the user or

10 the doctor. For example, a user or doctor can transcribe the stored information at a later time to determine compliance with the medical regimen or a comparison of analyte value levels to medication administration. This is accomplished by downloading the information to the display 102 through the display interface 208 and then transcribing all of the stored records at one time as they appear on the

15 display 208. In addition, the RAM 206 may also store updated program instructions and/or patient specific information.

In preferred embodiments, the microprocessor 216 is coupled to a data input and output (I/O) port 210 that uses the contacts 222 on the medical device module 200 to connect with the contacts 122 on the PDA 10, and the user can

20 download the stored information to an external computer (see Fig. 1), or the like, through the data I/O port 210 for evaluation, analysis, calibration, or the like. Preferably, the data I/O port 210 is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor. In preferred embodiments, the I/O port 210 uses the infrared (IR)

25 technology of the PDA 10 or may include its own IR transceivers similar to those shown and described in U.S. Patent No. 5,376,070 entitled "Data Transfer System for an Infusion Pump", or the like, which is herein incorporated by reference. However, in alternative embodiments, the I/O port 210 may use other data transfer technologies such as cables, fiber optics, RF, or the like. In still other

30 embodiments, the data I/O port 210 may include multiple ports to support multiple communication protocols or methods, or may include a universal port capable of transmitting data in several different modes. In preferred

embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) a computer, communication station, or the like. In alternative embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) an infusion pump, or the like.

5       The keypad interface 202 provides the user with the capability to set parameters in the medical device module using the keys 106 and 108 and/or display 102 of the PDA 10. Such capabilities include, but are not limited to, storing additional information, setting the date and the time, or setting alarms to indicate when to take the next test with the characteristic meter 300. The keypad  
10      interface 202 is used in conjunction with the display interface 208 to access the various modes, alarms, features, or the like, by utilizing methods typically employed to set the parameters on a conventional glucose meter, an infusion pump, or the like. Except this is all done through the use of a standard PDA interface.

15       The medical device module 200 also includes a self contained battery and power supply 218. Preferably, the medical device module 200 uses batteries (not shown) to provide power to the medical device module 200. For example, a plurality of silver oxide batteries, such as two or three, may be used. However, it is understood that different battery chemistries may be used, such as lithium, alkaline or the like, and different numbers of batteries can be used. In preferred embodiments, the batteries have a life in the range of 1 month to 1 year, and provide a low battery warning alarm. Alternative embodiments may provide longer or shorter battery lifetimes, or include a power port to permit recharging of rechargeable batteries in the medical device module 200. Further alternative  
20      embodiments may use the power supply (not shown) that is already included in the PDA 10 or recharge its own batteries through the power supplied by the cradle 22.

25       The ROM 204 of the medical device module 200 also stores additional programs to operate and control the characteristic meter 300. Moreover, the  
30      RAM 206 of the medical device module 200 can stores results obtained from the characteristic meter 300. As shown in Fig. 5, a test strip 350 for holding an analyte sample is inserted into the test interface 302. This activates the

characteristic test meter 304 and the microprocessor 216. The characteristic test meter 304 analyzes the characteristics and sends the analysis results to the microprocessor 216, which displays the results on the display 102 and stores the results in the RAM 206 for later review.

5       The programs for controlling the sensor monitor 212 of the characteristic monitor 200' are also stored in the ROM 204, and sensor data signal values received by the sensor interface 214 from the sensor set 150 are processed by the sensor monitor 212 and the microprocessor 216, and then the results are stored in the RAM 206. The sensor monitor 212 and the sensor interface 214 can be  
10      activated by a wired connection to a sensor set 150 that draws power from the characteristic monitor, by receipt of a signal from the telemetered characteristic monitor transmitter 100, or by the keys 106 and 108 and/or display 102 through the keypad interface 202. Preferred embodiments use a characteristic monitor 200' (in which the system includes a Potentiostat such as sensor monitor 212) to  
15      receive the sensor signals from a telemetered characteristic monitor transmitter 100, as shown in U.S. Patent Application Serial No. 09/377,472 entitled "Telemetered Characteristic Monitor System and Method of Using the Same", which is herein incorporated by reference. In alternative embodiments, the sensor signals may be received on a more infrequent (or periodic) basis from a Holter-  
20      type monitor system, as shown in U.S. Patent Application Serial No. 09/246,661 entitled "An Analyte Sensor and Holter-type Monitor System and Method of Using the Same", which is herein incorporated by reference.

Preferred embodiments store the raw received sensor signals values from the sensor monitor 212 and the test results from the characteristic test meter 304 25     of the characteristic meter in the RAM 206. However, alternative embodiments may also store calibrated and adjusted results in the RAM 206 for downloading, later analysis and review. Further embodiments may only store adjusted results.

Once activated, the sensor interface 214 continuously, intermittently or near continuously receives signals from the sensor set 150 that are representative 30     of an analyte level being monitored in a user. In preferred embodiments, the sensor monitor 212 is used in conjunction with the microprocessor 216 to store, smooth the data and determine a corresponding analyte level from the signals

received from the sensor interface 214. The corresponding value may be shown on the display 208. The characteristic monitor 200' of the medical device module 200 may also perform calibration of the sensor signal values using values provided by the characteristic meter 300. The calibration may be performed on a real-time basis and/or backwards recalibrated (e.g., retrospectively). In further embodiments, the microprocessor 216 monitors the sensor signals from the sensor monitor 212 to determine when the characteristic meter 300 should be used to perform tests to be used for calibration of the sensor data signals. For instance, the microprocessor 216 could indicate that the calibration test should be delayed if the sensor data signals from the sensor monitor 212 are changing too rapidly and suggest a calibration reading when the sensor data readings are relatively stable. Also, the characteristic monitor 200' of the medical device module 200 may prompt the user to perform calibration at periodic preset intervals. Alternatively, the characteristic monitor 200' of the medical device module 200 may prompt the user to perform the calibration based upon event-triggered intervals, that are either user input, such as meals, exercise, or the like, or that are trend input, such as large excursions in glucose levels, faulty or interrupted data readings, or the like.

As shown in Figs. 1-4, the PDA 10 includes a display 102 that is used to display the results of the measurement received from the sensor in the sensor set 150 via a cable and connector 180 attached to the telemetered characteristic monitor transmitter 100, or the like. The results and information displayed includes, but is not limited to, trending information of the characteristic (e.g., rate of change of glucose), graphs of historical data, average characteristic levels (e.g., glucose), or the like. Alternative embodiments include the ability to scroll through the data. The display 102 may also be used with the key 106 and 108 on the PDA 10 to program or update data in the medical device module 200. In addition, the calibrated data using results from the characteristic meter 300 can be displayed to provide a user with updated trend and glucose level data. This may also be used to update and show differences between the newly calibrated (or additional calibration) data and the data as it was prior to the new calibration (or additional calibration).

In other embodiments, if multiple characteristic sensors are used, the individual data for each characteristic sensor may be stored and displayed to show a comparison and an average between the two characteristic sensors.

It is noted that a typical user can have somewhat diminished visual and  
5 tactile abilities due to complications from diabetes or other conditions. Thus, the display 102 and/or keys 106 and 108 are preferably configured and adapted to the needs of a user with diminished visual and tactile abilities. In alternative embodiments, the data, analyte level value, confirmation of information, or the like can be conveyed to the user by audio signals, such as beeps, speech or the  
10 like, or vibrations. Further alternatives may include a microphone (not shown) and related circuitry to allow voice activated control of the infusion device.

Additional embodiments of the present invention may include a vibrator alarm (or optional indicator such as an L.E.D.) in either, or both, the telemetered characteristic monitor transmitter 100 and the medical device module 200 to  
15 provide a tactile (vibration) alarm to the user, such as sensor set 150 malfunction, improper connection, low battery, missed message, bad data, transmitter interference, or the like. The use of a vibration alarm provides additional reminders to an audio alarm, which could be important to someone suffering an acute reaction, or where it is desirable to have non-audio alarms to preserve and  
20 conceal the presence of the characteristic monitor system 10.

Figs. 7 and 8 show a second embodiment of the medical device module 200 may be used with a telemetered characteristic monitor transmitter 100 coupled to a sensor set 150 and an infusion pump 400 connected to an infusion set 450. In this embodiment, the medical device module 200 is also used to  
25 program and obtain data from the infusion pump 400, or the like. This further reduces the amount of equipment, the user must have, since the medical device module 200 already includes a characteristic monitor 200' and a characteristic meter 300 that will be required for calibration of the data from the telemetered characteristic monitor transmitter 100. Thus, the medical device module 200 can  
30 coordinate the sensor data and meter data with the data from the infusion pump 400, or update the delivery parameters of the infusion pump 400. The medical device module 200 may also be used to update and program the telemetered

characteristic monitor transmitter 100, if the transmitter 100 includes a receiver for remote programming, calibration or data receipt. Thus, the user may need only a single device - the medical device module 200 in the PDA 10 that will receive data from a sensor set 150, perform discrete tests of an analyte with the 5 characteristic meter 300, program and control an infusion pump 400, and operate to download data or upload programming instructions to a computer, communication station, or the like.

As discussed, the medical device module 200 can also be used to store data obtained from the sensor set 150 and then provide it to either an infusion 10 pump 400, computer or the like for analysis. In further embodiments, the medical device module 200 can include a modem, or the like, to transfer data to and from a healthcare professional. Further embodiments, can receive updated programming or instructions via a modem connection. In addition, a relay or repeater 4 may be used with a telemetered characteristic monitor transmitter 100 15 and a medical device module 200 to increase the distance that the telemetered characteristic monitor transmitter 100 can be used with the medical device module 200, as shown in the third embodiment of Fig. 9. For example, the relay 4 could be used to provide information to parents of children using the telemetered characteristic monitor transmitter 100 and the sensor set 150 from a 20 distance. The information could be used when children are in another room during sleep or doing activities in a location remote from the parents. In further embodiments, the relay 4 can include the capability to sound an alarm. In addition, the relay 4 may be capable of providing data from sensor set 150 and telemetered characteristic monitor transmitter 100 to a remotely located 25 individual via a modem connected to the relay 4 for display on a monitor, pager or the like. In alternative embodiments, the data from the medical device module 200 and sensor set 150 may also be downloaded through a communication station 8 (or alternatively, through a medical device module 200, other data transfer device, or the like) to a remotely located computer 6 such as a PC, lap top, or the 30 like, over communication lines, by modem or wireless connection, as shown in the fourth embodiment of Fig. 10. Also, some embodiments may omit the communication station 8 and use a direct modem or wireless connection to the

computer 6. In further alternatives, either the medical device module 200 or the telemetered characteristic monitor transmitter 100 may transmit an alarm to a remotely located device, such as a communication-station, modem or the like to summon help. In addition, further embodiments of the characteristic monitor 200' of the medical device module 200 may include the capability for simultaneous monitoring of multiple sensors. Data transmission may be to other devices or include the capability to receive data or instructions from other medical devices. Preferred embodiments, as shown in Figs. 1-8, use wireless RF frequencies; however, alternative embodiments may utilize IR, optical, ultrasonic, audible frequencies or the like. Further embodiments may also use a wired connection, as shown in Fig. 18.

Preferably, the PDA 10 uses a medical device module 200 that combines the characteristic monitor 200' and character meter 300 into a single device, but avoids an actual wired connection to the sensor set 150 by using a telemetered characteristic monitor transmitter 100. By separating the PDA 10 electronics into two separate devices; a telemetered characteristic monitor transmitter 100 (which attaches to the sensor set 150) and a characteristic monitor 200', several advantages are realized. For instance, the user can more easily conceal the presence of the PDA 10 and the telemetered characteristic monitor transmitter 100, since a wire will not be visible (or cumbersome), with clothing. It also makes it easier to protect the medical device module 200 with a characteristic monitor 200', which can be removed from the user's body during showers, exercise, sleep or the like. In addition, the use of multiple components (e.g., transmitter 100 and medical device module 200 with a characteristic monitor 200' with a characteristic meter) facilitates upgrades or replacements, since one module or the other can be modified or replaced without requiring complete replacement of the system. Further, the use of multiple components can improve the economics of manufacturing, since some components may require replacement on a more frequent basis, sizing requirements may be different for each module, there may be different assembly environment requirements, and modifications can be made without affecting the other components. For instance, the PDA 10 with its standard interface and other uses can be mass produced at

lower cost. And the medical device module 200 can be made to rigorous medical standards at lower cost than a complete device with an interface comparable to the PDA 10. This lowers the overall system costs, which permits quicker upgrades or design modifications. Thus, manufacturers can bring new devices 5 and/or options to market in less time and cost and with less risk.

Fig. 11 is a perspective view of a medical device module 500 that interfaces with a telemetered characteristic monitor transmitter 100 in accordance with a fifth embodiment of the present invention. This medical device module 500 includes a characteristic monitor 200' as described above, and communicates 10 with the telemetered characteristic monitor transmitter 100 to transfer data signals from a sensor set. This embodiment does not include a characteristic meter as described above. Preferably, the communication between the medical device module 500 and telemetered characteristic monitor transmitter 100 is wireless, as described above. However, in alternative embodiments, a wired connection such 15 as shown in Fig. 18 may be used. In further alternative embodiments, the medical device module 500 may also just act as a interface and communication device for the PDA 10 to receive processed data from the telemetered characteristic monitor transmitter 100, if the telemetered characteristic monitor transmitter 100 is a fully functional characteristic monitor that includes many of the functions of the 20 characteristic monitor 200' described above.

Fig. 12 is a perspective view of a medical device module 520 that interfaces with a characteristic meter 522 in accordance with a sixth embodiment of the present invention. Preferably, the communication between the medical device module 520 and characteristic meter 522 is wireless, as described above. 25 However, in alternative embodiments, a wired connection such as shown in Fig. 18 may be used. This embodiment does not include a characteristic monitor 200' or a characteristic meter 300 within the medical device module, as described above. Rather, this embodiment provides an interface with the PDA 10 and communication capability between the PDA 10 and the characteristic meter 522.

30 Fig. 13 is a perspective view of a medical device module 540 that interfaces with an infusion device 400, telemetered characteristic monitor transmitter 100 and a characteristic meter 522 in accordance with a seventh

embodiment of the present invention. This embodiment does not include a characteristic meter 300 within the medical device module, as described above. Rather, this embodiment provides an interface with the PDA 10 and communication capability between the PDA 10 and the telemetered characteristic monitor transmitter 100, the characteristic meter 522, and the infusion device 400. This medical device module 540 includes a characteristic monitor 200', and communicates with the telemetered characteristic monitor transmitter 100 to transfer data signals from a sensor set and the infusion device 400 as described above. Preferably, the communication between the medical device module 500 and telemetered characteristic monitor transmitter 100, the infusion device 400, and the characteristic meter 522 is wireless, as described above. However, in alternative embodiments, a wired connection such as shown in Fig. 18 may be used. In further alternative embodiments, the medical device module 500 may also just act as a interface and communication device for the PDA 10 to receive processed data from the telemetered characteristic monitor transmitter 100, if the telemetered characteristic monitor transmitter 100 is a fully functional characteristic monitor that includes many of the functions of the characteristic monitor 200' described above.

Fig. 14 is a perspective view of a medical device module 560 that includes a characteristic meter 300 and interfaces with an infusion device 400 in accordance with an eighth embodiment of the present invention. This embodiment does not include a characteristic monitor 200' within the medical device module, as described above. Rather, this embodiment provides an interface with the PDA 10 and communication capability between the PDA 10 and the infusion device 400. Preferably, the communication between the medical device module 560 and the infusion device 400 is wireless, as described above. However, in alternative embodiments, a wired connection such as shown in Fig. 18 may be used.

Fig. 15 is a perspective view of a medical device module 580 that includes a characteristic meter 300 in accordance with a ninth embodiment of the present invention. This embodiment does not include the characteristic monitor 200' as described above. It is primarily adapted to providing blood glucose test

capabilities to the PDA 10. Preferably, the test results and any relevant data input by the user can be downloaded, or updated program instructions can be uploaded to the medical device module 580 through either a wireless or wired connection.

Fig. 16 is a perspective view of a medical device module 600 that  
5 interfaces with an infusion device in accordance with a tenth embodiment of the present invention. This embodiment does not include a characteristic monitor 200' or a characteristic meter 300 within the medical device module, as described above. Rather, this embodiment provides an interface with the PDA 10 and communication capability between the PDA 10 and the infusion device 400.  
10 Preferably, the communication between the medical device module 600 and the infusion device 400 is wireless, as described above. However, in alternative embodiments, a wired connection such as shown in Fig. 18 may be used.

Fig. 17 is a perspective view of a medical device module 620 that  
interfaces with an implantable medical device 622 in accordance with a tenth  
15 embodiment of the present invention. Preferred embodiments of the implantable medical device 622 may be an infusion device, a characteristic monitor and/or sensor, a pacemaker, a neurostimulator, or the like. Generally, the devices are completely implanted in the body tissue 624 of a user. The medical device module 620 acts as an interface to the PDA 10 to communicate with and/or  
20 receive data from the implantable medical device 622. This embodiment is not shown with a characteristic monitor 200' or characteristic meter 300. However, alternative embodiments could include either or both with a characteristic monitor 200' or characteristic meter 300 as well as interfacing with the implantable medical device.

25 Fig. 18 is a perspective view of a medical device module 640 that includes a input jack 646 for a wired connection with a medical device 642 in accordance with an eleventh embodiment of the present invention. The medical device 642 can be any of the devices described herein. The medical device module 640 is coupled to a cable 644 through an input jack 646. The medical device 642 is also  
30 coupled to the cable 644 through an input jack 648 to complete the connection between the medical device module 640 and medical device 642. In particular embodiments, the medical device module 640 may include a modem, or the like,

for facilitating the transfer of data and/or information to the medical device 642. In further embodiments, the input jack 646 is an RS-232 port. However, different types of jacks, plugs and connectors may be used. In alternative embodiments, the medical device module 640 may also include the capability to transfer data and/or information by wireless communication, as described above.

Fig. 19 is a perspective view of a medical device module 660 that interfaces with an implantable analyte sensing patch 662 in accordance with a twelfth embodiment of the present invention. As shown, the implantable patch 662 is generally implanted under the skin 664 of the user. However, in alternative embodiments, the implantable patch may be implanted in other body tissue, as described above, or attached to the skin surface of the user. Preferably, the implantable patch 662 includes a photo-reactive substance or compound 76 that optically changes, fluoresces, or the like, or other suitable compounds that detect changing properties in the presence of a bodily fluid analyte, such as glucose or the like. The compounds can also be used to detect the level of an analyte that has been ingested, injected or placed inside the body, such as marker substances, or the like. For example, possible compounds, including but not limited to, produce a fluorescent change in the presence of a bodily fluid analyte are disclosed in U.S. Patent No. 5,503,770 issued April 2, 1996 to James et al. and entitled "Fluorescent Compound Suitable For Use In The Detection Of Saccharides"; U.S. Patent No. 5,512,246 issued April 30, 1996 to Russell et al. and entitled "Method and Means for Detecting Polyhydroxyl Compounds"; U.S. Provisional Application Serial No. 60/007,515 to Van Antwerp et al. and entitled "Minimally Invasive Chemically Amplified Optical Glucose Sensor"; and U.S. Patent No. 6,011,984 to Van Antwerp et al. and entitled "Detection of Biological Molecules Using Chemical Amplification", all of which are herein incorporated by reference. Other compounds using Donor Acceptor fluorescent techniques may be used, such as disclosed in U.S. Patent No. 5,628,310 issued May 13, 1997 to Rao et al. and entitled "Method and Apparatus to Perform Trans-cutaneous Analyte Monitoring"; U.S. Patent No. 5,342,789 issued August 30, 1994 to Chick et al. and entitled "Method and Device for Detecting and Quantifying Glucose in body Fluids"; and U.S. Patent No. 5,246,867 issued September 21, 1993 to

Lakowicz et al. and entitled "Determination and Quantification of Saccharides by Luminescent Lifetimes and Energy Transfer", all of which are herein incorporated by reference. In still further embodiments, the medical device module may interface with the implantable patch using other communication methods, such as  
5 RF or the like.

Fig. 20 is a perspective view of a medical device module 680 that includes contacts 684 for interfacing with a medical device 682 in accordance with a thirteenth embodiment of the present invention. The medical device 682 can be any of the devices described herein. The medical device module 680 is coupled  
10 to the medical device 682 by contact 684 being coupled with corresponding contacts 686 on the medical device 682 to complete the connection between the medical device module 680 and medical device 682. In particular embodiments, the contacts 684 and 686 establish a connection by simply lining up and putting the two device together. In other embodiments, the contacts 684 and 686 are  
15 physically coupled together to reduce the likelihood that the connection will be accidentally terminated. In other embodiments, the contacts 684 are used as electrodes to measure electrical characteristics of the user. For instance, the contacts may be placed against the skin of the user to measure pulse, heart rate, sweat effects, or the like. This embodiment may utilize a wired or wireless  
20 connection to transfer data received through the contacts 684 of the medical device monitor 680 to another medical device, or the like.

While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended  
25 to cover such modifications as would fall within the true scope and spirit of the present invention.

The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than the foregoing description, and all  
30 changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

WHAT IS CLAIMED IS:

1. A medical device module for use in a system with a personal data assistant (PDA) with at least one medical device, the medical device module comprising:
  - 5 a housing adapted to couple with the PDA;
  - at least one medical device interface coupled to the housing for interfacing with the at least one medical device; and
  - a processor coupled to the at least one medical device interface to process data from the at least one medical device, and wherein the processor is capable of
  - 10 interfacing with the PDA.
2. The medical device module according to claim 1, wherein the at least one medical device is a characteristic sensor that produces a signal indicative of a characteristic of a user, and further comprising:
  - 15 a second characteristic determining device within the housing for receiving and testing an analyte to determine the quantity of the analyte independently of the at least one characteristic sensor; and
  - wherein the at least one medical device interface is a sensor receiver to receive sensor data signals produced from the at least one characteristic sensor,
  - 20 and
  - wherein the processor is coupled to the sensor receiver and the second characteristic determining device to process the determined quantity of the analyte from the second characteristic determining device and the sensor data signals from the at least one characteristic sensor.
- 25 3. The medical device module according to claim 2, wherein the at least one characteristic sensor is remotely located from the medical device module, and wherein the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor.

30

4. The medical device module according to claim 2, further including a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device.
5. 5. The medical device module according to claim 2, wherein the medical device module uses a display of the PDA to show the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor.
- 10 6. The medical device module according to claim 2, wherein the processor monitors the sensor data signals from the sensor receiver to determine when the second characteristic determining device is to be used to perform calibration of the sensor data signals.
- 15 7. The medical device module according to claim 2, further including a memory to store the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor.
- 20 8. The medical device module according to claim 2, wherein the sensor data signals are received by the sensor receiver continuously.
9. The medical device module according to claim 2, wherein the sensor data signals are received by the sensor receiver near continuously.

25

10. The medical device module according to claim 2, wherein the sensor data signals are received by the sensor receiver intermittently.
11. The medical device module according to claim 2, wherein the second characteristic determining device is a second medical device module that utilizes a second characteristic sensor.

12. The medical device module according to claim 11, wherein the determined quantity of the analyte from the second characteristic determining device is determined continuously.
- 5 13. The medical device module according to claim 11, wherein the determined quantity of the analyte from the second characteristic determining device is determined near continuously.
- 10 14. The medical device module according to claim 11, wherein the determined quantity of the analyte from the second characteristic determining device is determined intermittently.
- 15 15. The medical device module according to claim 11, wherein the second medical device module and the second characteristic sensor use a different sensing technology from that used by the at least one medical device module and the characteristic sensor.
- 20 16. The medical device module according to claim 2, wherein the second characteristic determining device utilizes a discrete sample to determine the quantity of the analyte.
- 25 17. The medical device module according to claim 16, wherein the second characteristic determining device utilizes a test strip to analyze the sample to determine the quantity of the analyte.
18. The medical device module according to claim 1, wherein the at least one medical device is an infusion device.
- 30 19. The medical device module according to claim 1, wherein the at least one medical device is an analyte sensor patch.

20. The medical device module according to claim 1, wherein the at least one medical device is more than one medical device.

21. A personal data assistant (PDA) for interfacing with at least one medical device, the PDA comprising:

medical device module to operatively couple with the PDA and including:

a housing adapted to couple with the PDA;

at least one medical device interface coupled to the housing for interfacing with the at least one medical device; and

10 a processor coupled to the at least one medical device interface to process data from the at least one medical device, and wherein the processor is capable of interfacing with the PDA, and

wherein the PDA includes a housing adapted to receive the medical device module.

15

22. The PDA according to claim 21, wherein the at least one medical device is a characteristic sensor that produces a signal indicative of a characteristic of a user, and further comprising:

a second characteristic determining device within the housing for

20 receiving and testing an analyte to determine the quantity of the analyte independently of the at least one characteristic sensor; and

wherein the at least one medical device interface is a sensor receiver to receive sensor data signals produced from the at least one characteristic sensor, and

25 wherein the processor is coupled to the sensor receiver and the second characteristic determining device to process the determined quantity of the analyte from the second characteristic determining device and the sensor data signals from the at least one characteristic sensor.

23. The PDA according to claim 22, wherein the at least one characteristic sensor is remotely located from the medical device module, and wherein the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor.

5

24. The PDA according to claim 22, further including a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device.

10 25. The PDA according to claim 22, wherein the medical device module uses a display of the PDA to show the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor.

15 26. The PDA according to claim 22, wherein the processor monitors the sensor data signals from the sensor receiver to determine when the second characteristic determining device is to be used to perform calibration of the sensor data signals.

20 27. The PDA according to claim 22, further including a memory to store the determined quantity of the analyte from the second characteristic determining device and the processed sensor data signals from the at least one characteristic sensor.

25 28. The PDA according to claim 22, wherein the sensor data signals are received by the sensor receiver continuously.

29. The PDA according to claim 22, wherein the sensor data signals are received by the sensor receiver near continuously.

30

30. The PDA according to claim 22, wherein the sensor data signals are received by the sensor receiver intermittently.

31. The PDA according to claim 22, wherein the second characteristic determining device is a second medical device module that utilizes a second characteristic sensor.
- 5 32. The PDA according to claim 31, wherein the determined quantity of the analyte from the second characteristic determining device is determined continuously.
- 10 33. The PDA according to claim 31, wherein the determined quantity of the analyte from the second characteristic determining device is determined near continuously.
- 15 34. The PDA according to claim 31, wherein the determined quantity of the analyte from the second characteristic determining device is determined intermittently.
- 20 35. The PDA according to claim 31, wherein the second medical device module and the second characteristic sensor use a different sensing technology from that used by the at least one medical device module and the characteristic sensor.
- 25 36. The PDA according to claim 22, wherein the second characteristic determining device utilizes a discrete sample to determine the quantity of the analyte.
- 30 37. The PDA according to claim 36, wherein the second characteristic determining device utilizes a test strip to analyze the sample to determine the quantity of the analyte.
38. The PDA according to claim 21, wherein the at least one medical device is an infusion device.

39. The PDA according to claim 21, wherein the at least one medical device is an analyte sensor patch.

40. The PDA according to claim 21, wherein the at least one medical device is  
5 more than one medical device.

41. A medical device module for use in a system with a personal data assistant (PDA) with at least one characteristic sensor that produces a signal indicative of a characteristic of a user, the medical device module comprising:  
10 a housing adapted to operatively couple with the PDA;  
a test strip receptacle for receiving and testing a test strip exposed to an analyte to determine the quantity of the analyte;  
a sensor receiver to receive sensor data signals produced from the at least one characteristic sensor; and  
15 a processor coupled to the sensor receiver and the test strip receptacle to process the determined quantity of the analyte from the test strip receptacle and the sensor data signals from the at least one characteristic sensor, and wherein the processor is capable of interfacing with the PDA.

20 42. The medical device module according to claim 41, wherein the at least one characteristic sensor is remotely located from the medical device module, and wherein the sensor receiver receives the sensor data signals as wireless signals from the remotely located at least one characteristic sensor.

25 43. The medical device module according to claim 41, further including a transmitter coupled to the processor for transmitting the processed sensor data signals to another data receiving device.

44. The medical device module according to claim 43, wherein the transmitter  
30 transmits the processed sensor signals by radio frequencies.

45. The medical device module according to claim 43, wherein the processor further includes the ability to program other medical devices, and wherein the transmitter transmits a program to the other medical devices.

5 46. The medical device module according to claim 43, wherein the transmitter transmits through a relay device between the transmitter and a remotely located processing device.

10 47. The medical device module according to claim 46, wherein the relay device increases a maximum distance by amplifying the processed sensor data signals from the transmitter to be received by the remotely located processing device.

15 48. The medical device module according to claim 47, wherein the relay device enables the remotely located processing device to be located in a different room than the transmitter.

20 49. The medical device module according to claim 46, wherein the relay device includes a telecommunications device, and wherein when the transmitter generates an alarm the telecommunications device transmits the alarm to a remotely located receiving station.

25 50. The medical device module according to claim 41, further including a data receiver, and wherein the data receiver receives program instructions from other processing devices.

.51. The medical device module according to claim 41, wherein the medical device module uses a display of the PDA to show the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor.

52. The medical device module according to claim 41, wherein the processor monitors the sensor data signals from the sensor receiver to determine when the test receptacle is to be used to perform calibration of the sensor data signals.
- 5 53. The medical device module according to claim 41, further including a memory to store the determined quantity of the analyte from the test strip receptacle and the processed sensor data signals from the at least one characteristic sensor.
- 10 54. The medical device module according to claim 41, wherein the sensor data signals are received by the sensor receiver continuously.
55. The medical device module according to claim 41, wherein the sensor data signals are received by the sensor receiver near continuously.
- 15 56. The medical device module according to claim 41, wherein the sensor data signals are received by the sensor receiver intermittently.

1/8

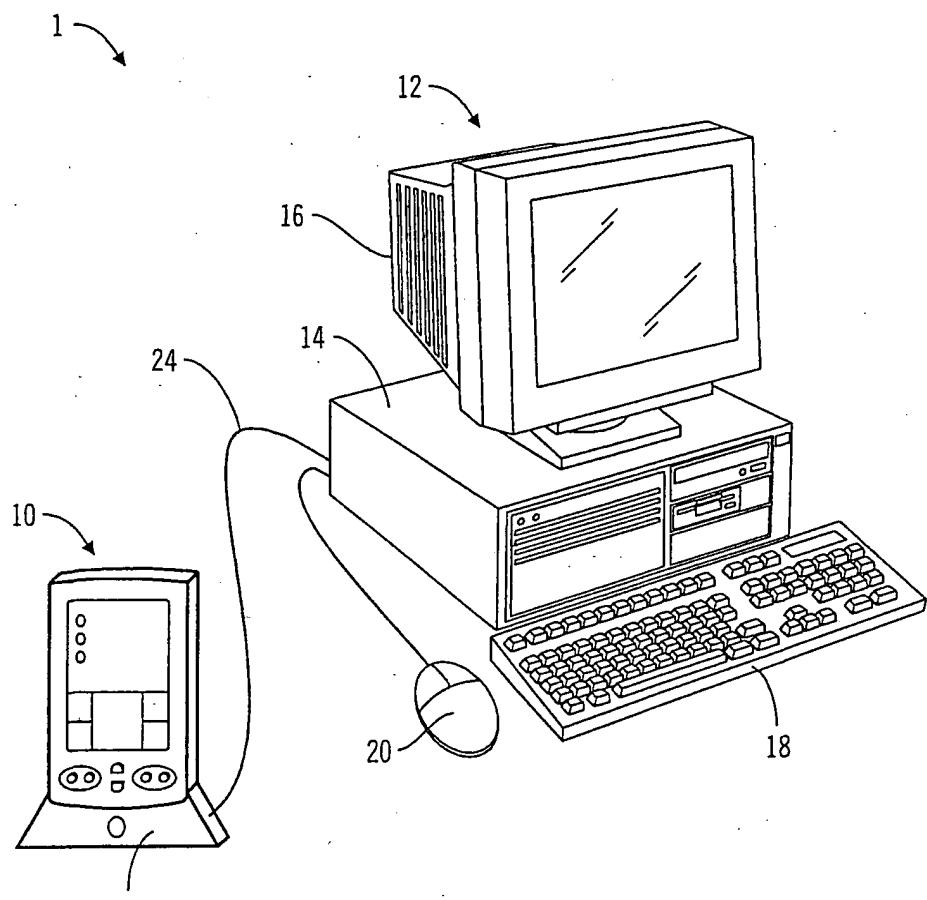


FIG. 1

SUBSTITUTE SHEET (RULE 26)

2/8

FIG. 2

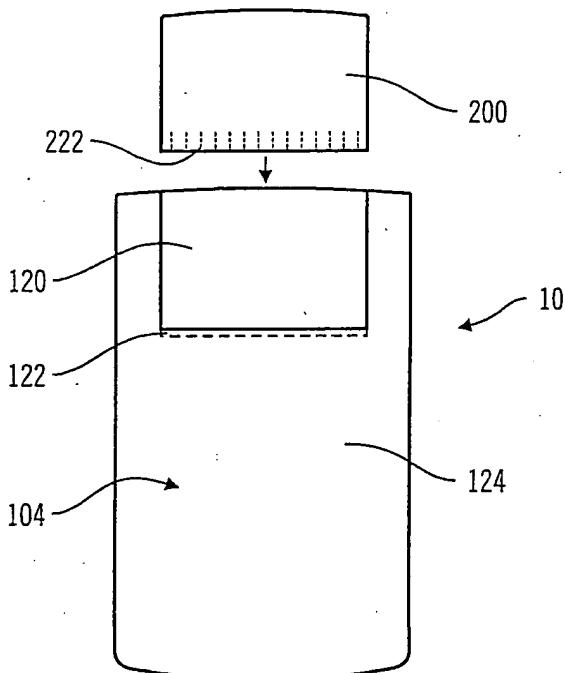
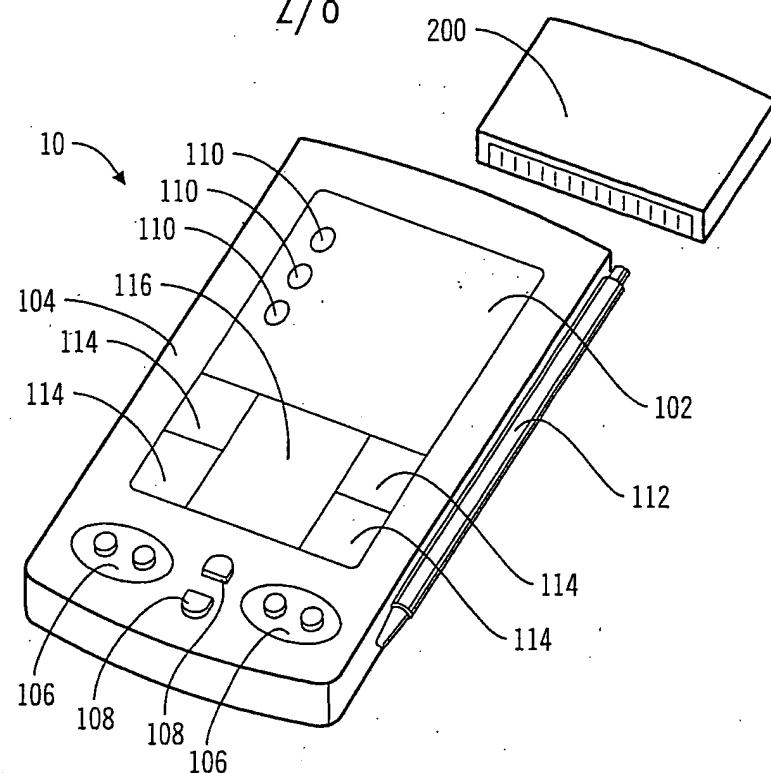


FIG. 3

3/8

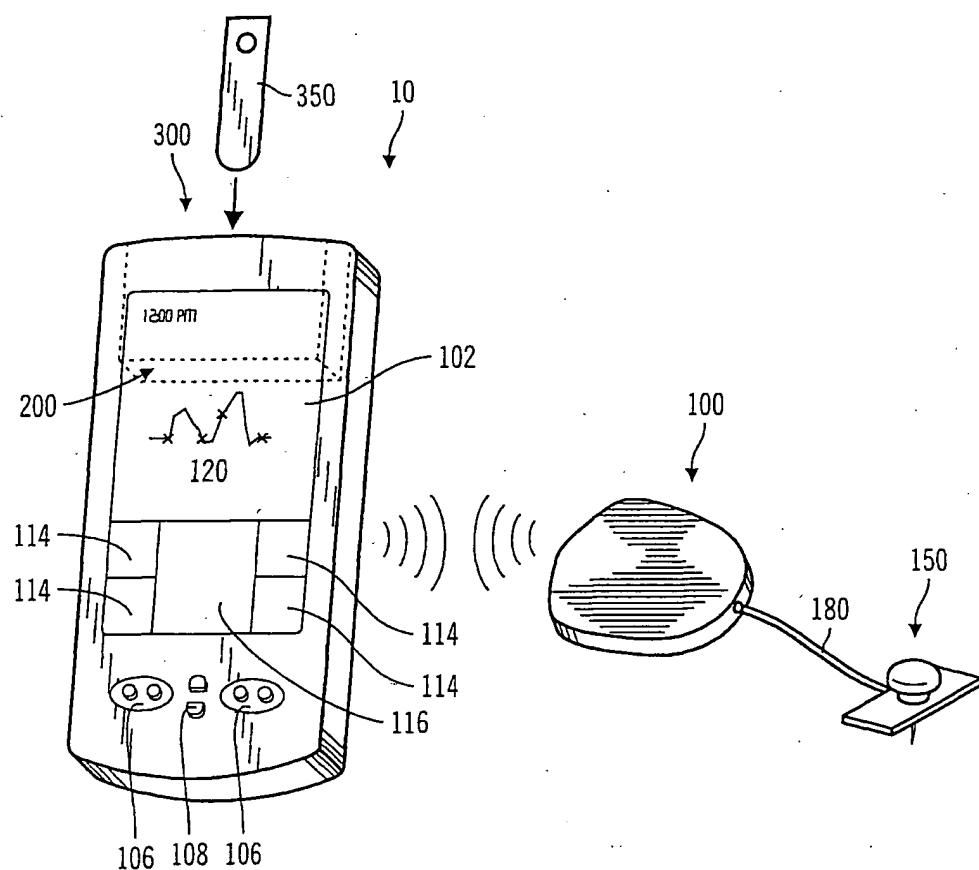


FIG. 4

SUBSTITUTE SHEET (RULE 26)

4/8

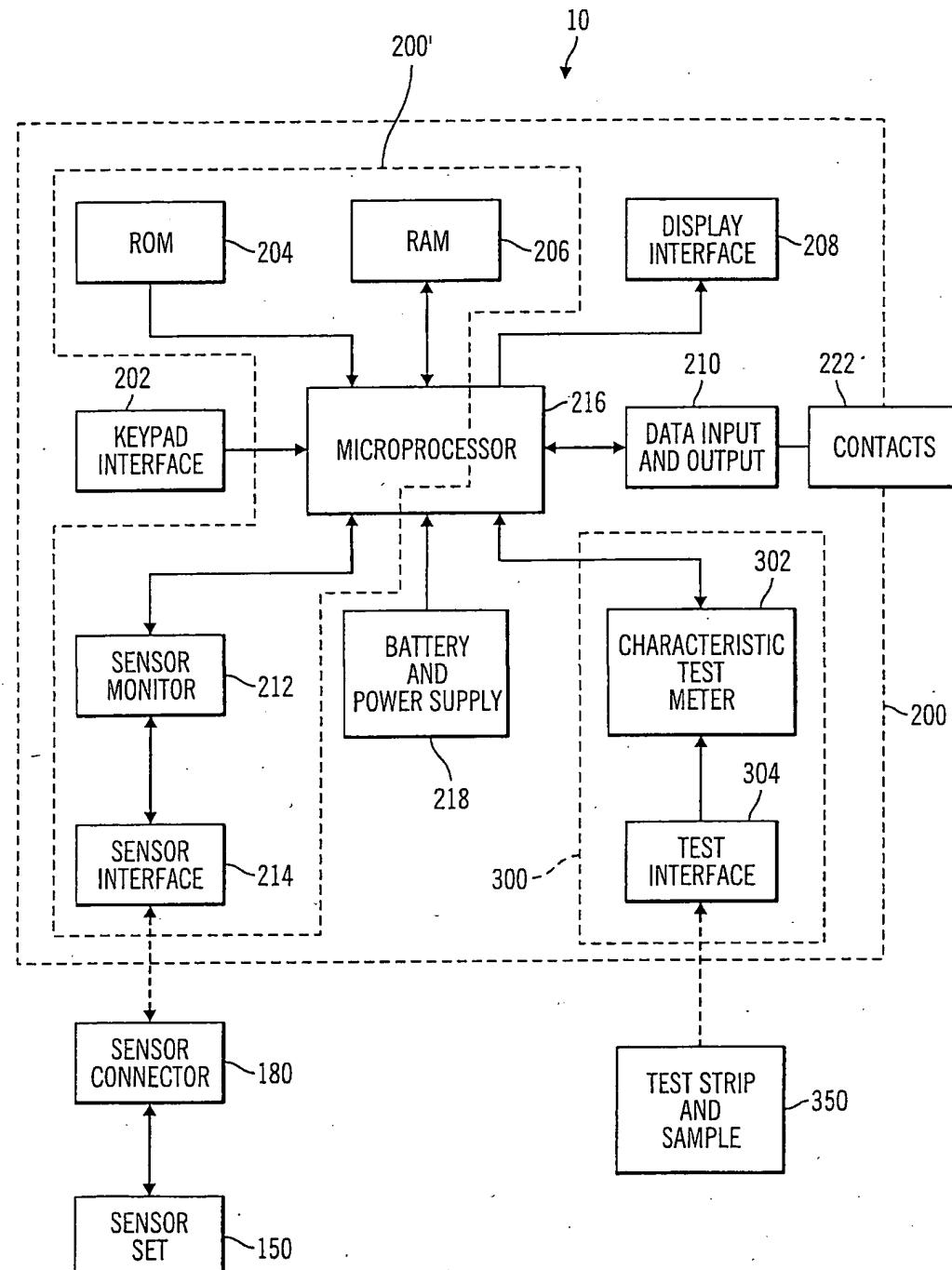
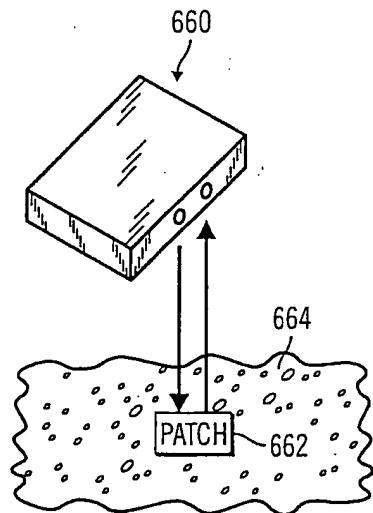
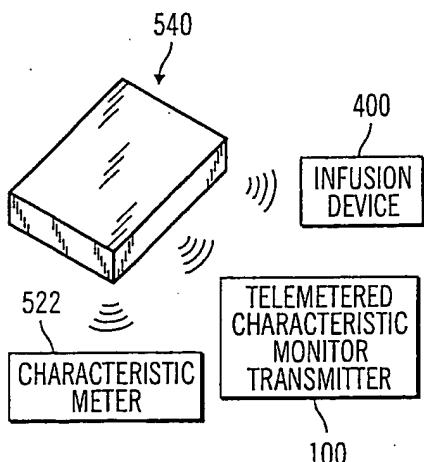
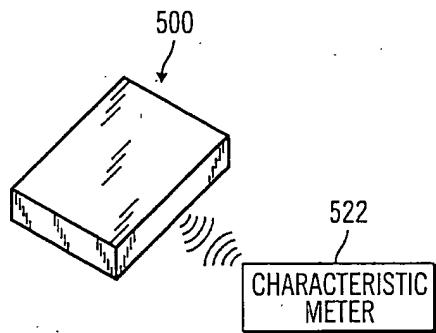
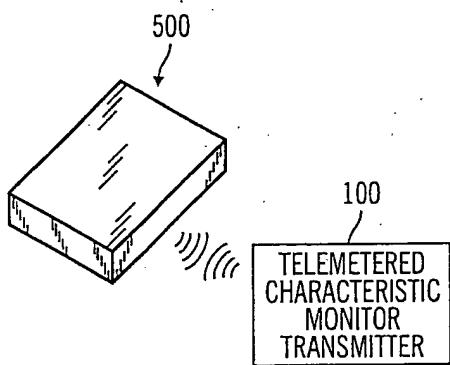
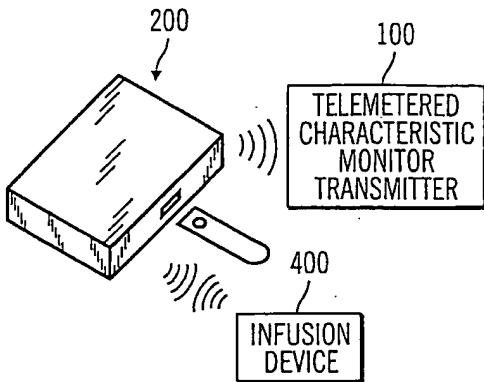
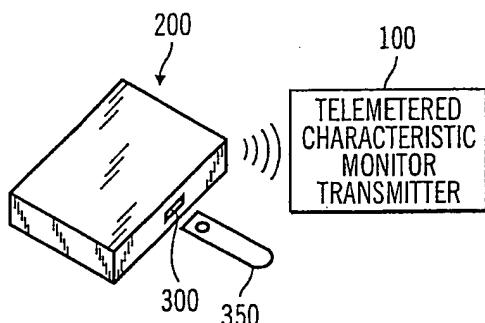


FIG. 5

5/8



6/8

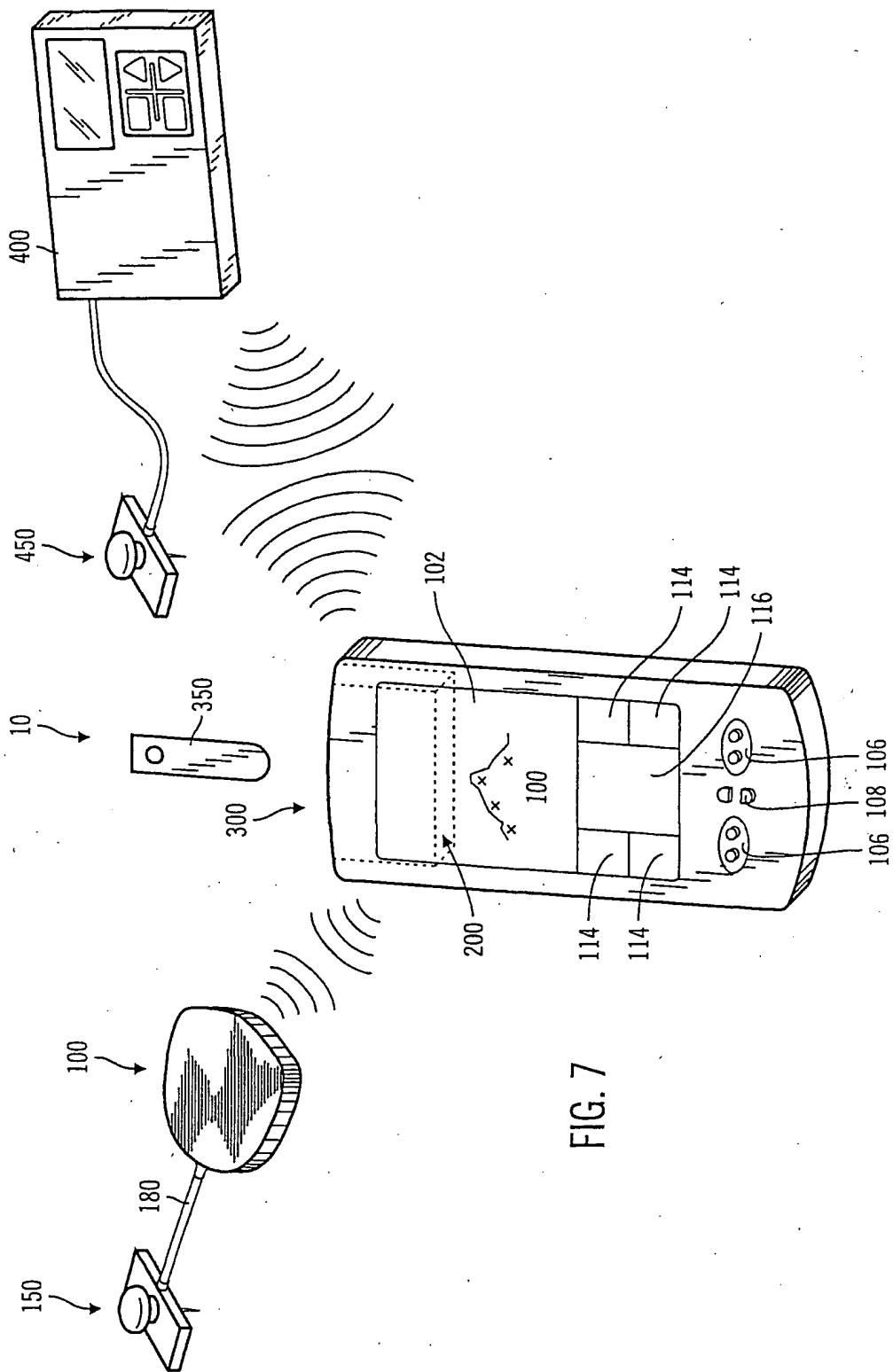


FIG. 7

7/8

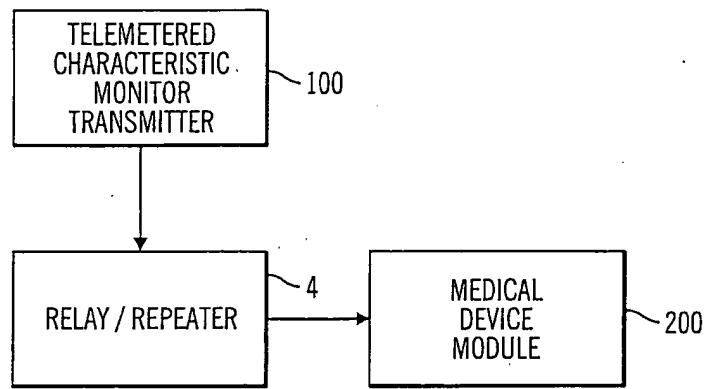


FIG. 9

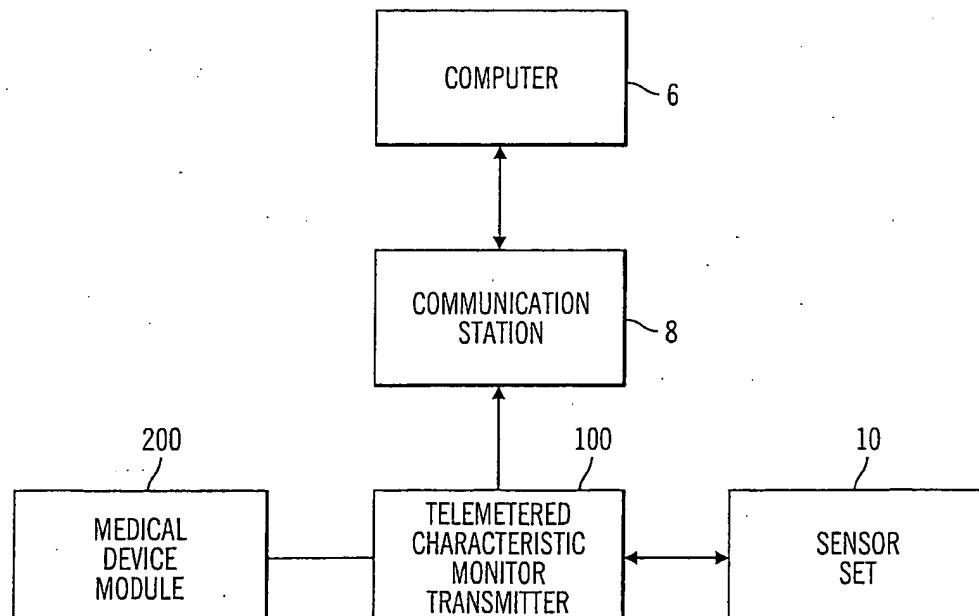


FIG. 10

8/8

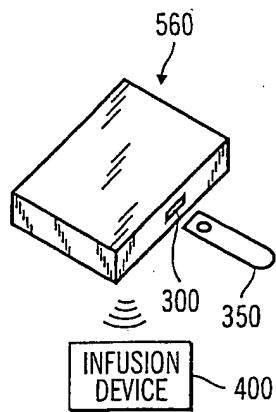


FIG. 14

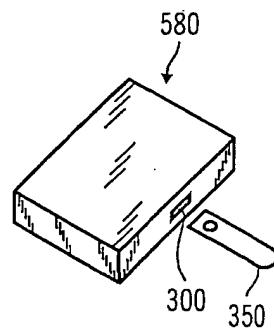


FIG. 15

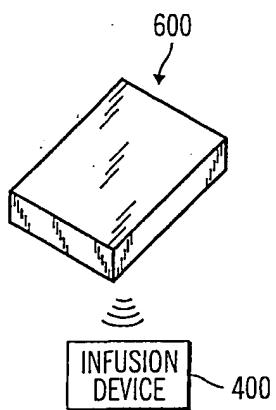


FIG. 16

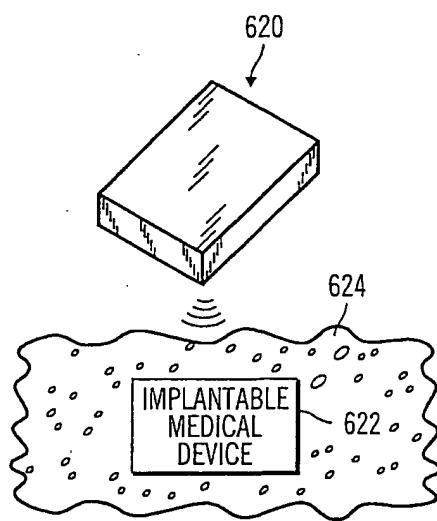


FIG. 17

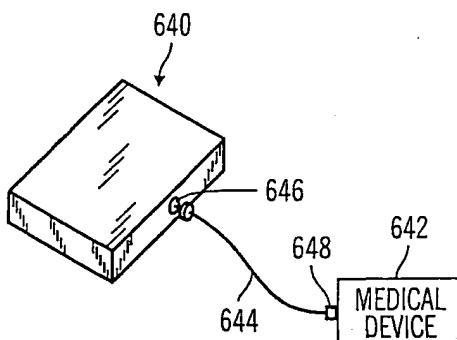


FIG. 18

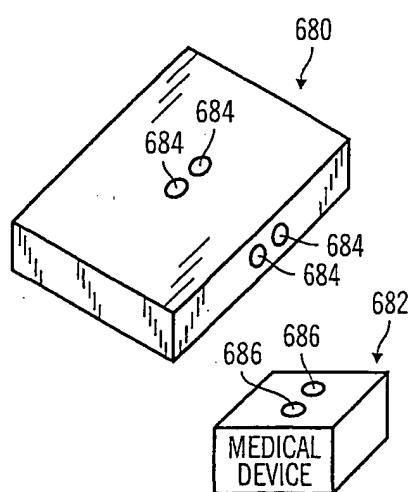


FIG. 20

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/01670

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 507 288 A (BLASBERG PETER ET AL) 16 April 1996 (1996-04-16)	1-8, 10-12, 14-17, 20, 22-28, 30-32, 34-37, 40-43, 45, 50-54, 56
A	column 5, line 17 -column 8, line 60; tables 1,2 -/-	9, 13, 29, 33, 44, 55

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the International search report
27 April 2001	09/05/2001
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  Weihs, J

## INTERNATIONAL SEARCH REPORT

Internat'l Application No

PCT/US 01/01670

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 880 936 A (AKAI KOJI) 2 December 1998 (1998-12-02)  column 3, line 29 -column 4, line 16 column 4, line 34 -column 7, line 40; tables 1-3 ----	1, 3-5, 8, 10, 21, 23, 25, 28, 30
A	WO 97 28736 A (NOKIA MOBILE PHONES LTD ;OKKONEN HARRI (FI); HEINONEN PEKKA (FI)) 14 August 1997 (1997-08-14)  page 6, line 17 -page 11, line 10; tables 1-4 ----	1-17, 21-37, 41-45, 53, 54
P, X	WO 00 78210 A (MINIMED INC) 28 December 2000 (2000-12-28) page 6, line 12 -page 15, line 20; tables 1-6 ----	1-56
P, X	WO 00 19887 A (MINIMED INC) 13 April 2000 (2000-04-13)	1, 3, 4, 18, 21, 23, 38, 44
A	abstract  page 2, line 21 -page 3, line 24 page 5, line 15 -page 8, line 13; tables 1, 2, 13, 14 ----	41, 42, 46-49

## INTERNATIONAL SEARCH REPORT

Information on patent family members.

International Application No

PCT/US 01/01670

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 5507288	A	16-04-1996		DE 4415896 A		09-11-1995
				AU 674474 B		19-12-1996
				AU 1763495 A		07-12-1995
				CA 2148569 A		06-11-1995
				CN 1128353 A		07-08-1996
				EP 0680727 A		08-11-1995
				FI 952131 A		06-11-1995
				HU 75243 A		28-05-1997
				IL 113569 A		04-01-1998
				JP 7311196 A		28-11-1995
				KR 163476 B		15-12-1998
				NO 951754 A		06-11-1995
				NZ 272000 A		24-04-1997
				ZA 9503585 A		04-11-1996
EP 0880936	A	02-12-1998		JP 10328170 A		15-12-1998
				JP 11104088 A		20-04-1999
WO 9728736	A	14-08-1997		FI 960636 A		13-08-1997
				AU 1726697 A		28-08-1997
				EP 0959755 A		01-12-1999
				JP 2000504597 T		18-04-2000
				US 5772586 A		30-06-1998
WO 0078210	A	28-12-2000		NONE		
WO 0019887	A	13-04-2000		AU 6255699 A		26-04-2000